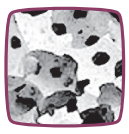


Actifuse Flow

Bone Graft Substitute

Silicate Substituted Calcium Phosphate

0714689

INSTRUCTIONS FOR USE
IMPORTANT PRODUCT INFORMATION

Please read before use

SPINAL / ORTHOPEDIC APPLICATIONS

Product Description

Actifuse Flow contains Actifuse, an osteostimulatory, phase-pure, porous, silicate substituted calcium phosphate bone graft substitute. Actifuse contains 0.8% silicon by weight, similar levels to those identified in naturally-growing bone. Calcium phosphate bone graft substitutes have been the topic of extensive clinical studies for several decades. Actifuse Flow is safe and has excellent biocompatibility. The interconnected macro- and micro- porous structure and enhanced surface chemistry of Actifuse Flow encourages the rapid formation of host bone and the growth of capillary blood vessels throughout the network of interconnecting pores. Actifuse is osteostimulatory based upon in vitro studies that show that cellular responses, such as metabolic activity and proliferation, are accelerated when compared to an identical material that did not contain 0.8% silicon by weight. After it is implanted, Actifuse undergoes physiologically-mediated resorption and is replaced by natural bone. Actifuse has a resorption time that lies between the least soluble pure Hydroxyapatite and the most soluble form of tricalcium phosphate.

Actifuse Flow is supplied in a sterile polypropylene syringe and contains Actifuse granules, with 80% (±2.5%) porosity and a granule size range of 0.09 – 0.5 mm, suspended in an aqueous gel carrier. **Actifuse Flow does not set in-situ following implantation. Actifuse Flow does not contain antibiotics.** The bioactive and osteostimulatory nature of Actifuse has not been correlated with human clinical experience.

Indications For Use

Actifuse Flow is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse Flow can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Contraindications

Actifuse Flow is not designed or sold for any use except as indicated. Do not use Actifuse Flow in the presence of any contraindication. Actifuse Flow is contraindicated where the device is intended as structural support in the skeletal system. Actifuse Flow is contraindicated for use in the treatment of vertebral compression fractures.

Other conditions representing contraindications include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcaemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

Warnings

Actifuse Flow is not intended for load-bearing uses. It is important to ensure that the area where Actifuse Flow has been implanted be properly secured mechanically with rigid fixation to strengthen the surroundings. Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of Actifuse Flow on patients with the following conditions is unknown:

- documented renal disease
- metabolic bone disease
- pregnancy and nursing
- radiation bone therapy
- long-term infection
- cardiovascular disease precluding elective surgery.

The effect of Actifuse Flow in pediatric patients is not known. **The effect of mixing Actifuse Flow with substances other than sterile saline/water, autologous blood or bone marrow aspirate is unknown.**

Possible Complications

Successful results may not be achieved in every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- wound complications including hematoma, edema, swelling and fluid accumulation, fever, inflammation, cyst, tissue thinning, bone fracture, infection, and other complications that are possible with any surgery
- fracture of the implant with or without generation of particulate debris
- inadequate bone formation, protrusion, dislodgement, migration, or extravasation (leakage), allergic/immune response or other complications associated with bone void fillers
- bone deformity at the site
- delayed or non-union / lack of osseointegration
- transient hypercalcaemia.

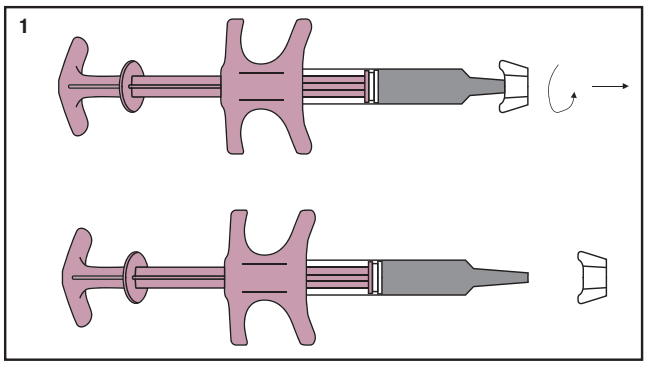
Precautions

Content of package is STERILE by prior exposure to gamma radiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
Actifuse Flow is opaque to x-rays. This may mask areas under or above the implant on a radiograph.
The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
Fully fill the bony defect ensuring maximal contact between Actifuse Flow and the host bone.
Do not overfill or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fat embolization or embolization of the device into the bloodstream.
Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.

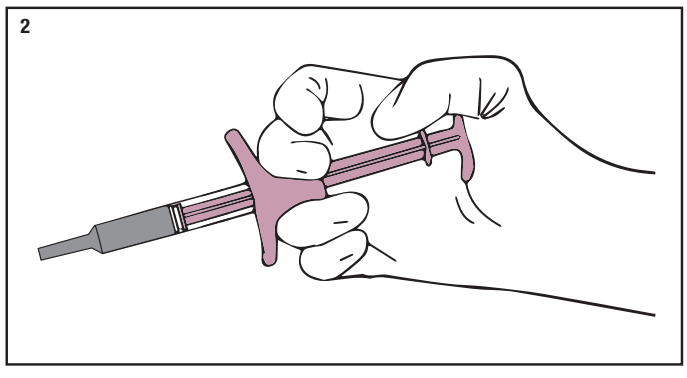
Instructions for use:

Step 1. Open both the outer (non-sterile) pouch and inner (sterile) packaging.
Step 2. Remove syringe cap gently depress the syringe plunger using a palm grip as shown in pictures 1 and 2 below to expel Actifuse Flow from the syringe. Dispense Actifuse Flow into the bony defect site and make sure maximal contact between Actifuse Flow and the host bone. Do not use too much force when placing applicator tip on defect site. This may result in bending of the applicator tip leading to restriction of Actifuse Flow through the applicator tip. Actifuse Flow is designed to be used alone.
Step 3. Implant. Secure the surgical site after implanting to prevent micro-motion and implant migration. When excess fluid is present at the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of Actifuse Flow.

1



2



Storage, Shelf Life and Disposal

Product should be stored between 10 – 70% Relative Humidity and 5 – 32°C (40 – 90°F).
The expiration date is printed on the label. DO NOT USE ACTIFUSE FLOW AFTER THE EXPIRATION DATE.
Actifuse Flow is environmentally friendly. No special disposal is necessary.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital.
Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Actifuse Flow, and for the choice of post-operative follow-up procedures rests entirely with the physician.

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